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when present in the cytoplasm of a pancreatic cell, to inhibit or block enzymatic secretion by said pancreatic cell, and wherein following binding of said first element to a pancreatic acinar cell said third element is transported across a pancreatic cell membrane.

REMARKS

This communication is being filed in reply to the Office Action mailed May 21, 2002. Applicants have carefully studied the Examiner's comments, and have the following remarks.

Rejection of Claims 1-24 under 35 USC § 112(1)

The Examiner has rejected pending claims 1-24 as being allegedly in violation of the written description requirement of 35 USC 112(1). Applicants respectfully traverse this rejection as it may be held to apply to the present claims. Applicants also note that, while they have amended the claims in order to expedite allowance of claims from this patent application, they do not agree that subject matter present in the claims before this amendment was in violation of the written description requirement, and reserve the right to pursue such subject matter at a later time.

The claims now recite a binding element comprising a peptide containing an amino acid sequence region SEQ ID NO. 2 or a contiguous fragment thereof containing at least the 8 C-terminal residues of such region, wherein the C-terminal phenylalanine is amidated and/or the aspartic acid residue 7 amino acids from the C-terminus thereof is sulfated, or an unmodified derivative hereof. The specification presents the entire amino acid sequence of SEQ ID NO: 2, which is 58 amino acids in length. The specification also states that "CCK is . . . post-translationally cleaved into a number of active fragments all sharing the same C-terminus." Specification, page 16, lines 18-21. Examples of such fragments are disclosed in SEQ ID NO: 3-6. Specification at page 17. Amidation and sulfation of the phenylalanine and aspartic acid residues, respectively, is also disclosed on page 17.

Thus, there can be no reasonable doubt that amended claim 1, as well as the claims dependent thereupon, are fully described so as to inform the person of skill in the art that the present Applicants are the inventors of the claimed subject matter. Specifically, from SEQ ID NO.: 2 and the phrase quoted above from the specification, the person of ordinary skill in the art would be able to determine the structure of the set of peptides comprised in the claimed composition.

For this reason applicants respectfully request that the Examiner reconsider the rejection of claims 1-24 in light of the present remarks and amendments and permit the claims to proceed to issue.

CONCLUSION

For the reasons given above, Applicants believe the pending claims are in ;condition for allowance, and respectfully request that the Examiner issue a Notice to that effect. If any fee is required in connection with this communication; please use Deposit Account 01-0885 for payment of any fee that may be due.

Respectfully submitted,

Date: 8/16/02

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MARKED-UP COPY OF AMENDED CLAIM

1. (5 times amended) A composition able to treat acute pancreatitis in a mammal comprising,

a) a first element comprising a binding element selected from the group consisting of a) a first peptide containing an amino acid sequence region SEQ ID NO. 2 or a contiguous fragment thereof containing at least the 8 C-terminal residues of such region, wherein the C-terminal phenylalanine is amidated and/or the aspartic acid residue 7 amino acids from the C-terminus thereof is sulfated, and b) said first peptide wherein said phenylalaninre and aspartic acid residue have not been modified, and wherein said binding element is able to specifically bind a CCK-A or CCK-B receptor under physiological conditions,

b) a second element comprising a translocation element derived from a Clostridial neurotoxin able to facilitate the transfer of a polypeptide across a vesicular membrane in a pancreatic cell, and

c) a third element, linked to and comprised in a separate polypeptide chain from said first and second elements, comprising a therapeutic element derived from a Clostridial neurotoxin able, when present in the cytoplasm of a pancreatic cell, to inhibit or block enzymatic secretion by said pancreatic cell, and wherein following binding of said first element to a pancreatic acinar cell said [composition] third element is transported across a pancreatic cell membrane.